K080272

MAR 11 2008

510(k) Summary of Safety and Effectiveness

Boston Scientific Corporation

Atlantis™ PV Imaging Catheter

Submitted By

Boston Scientific Corporation
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Contact Person

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Date Prepared

January 31, 2008

Proprietary Name

Atlantis™ PV Imaging Catheter

Common Name(s)

Ultrasonic Diagnostic Transducer
Ultrasonic Intravascular Catheter

Classification Name(s)

21 CFR 892.1570 (ITX)
Transducer, Ultrasonic, Diagnostic
21 CFR 870.1200 (OBJ)
Catheter, Ultrasound Intravascular

Predicate Device

The Atlantis™ PV Imaging Catheter is substantially equivalent to the following predicate device:

Name	Manufacturer	510(k) Number
Atlantis™ PV Imaging Catheter	Boston Scientific Corporation	K050684

Description of the Device

The Atlantis™ PV imaging catheter (H749364560) is a sterile, single use, over-the-wire (OTW) imaging catheter with a 8F distal crossing profile and a transducer capable of producing a frequency of 15MHz and a 8F distal crossing profile. This imaging catheter is designed to be operated with Boston Scientific Corporation (BSC) Intravascular Ultrasound Imaging Systems: iLab™ (K072517), Galaxy2/Galaxy™ (K980851), and Clearview™ Ultra (K921750).

The Atlantis™ PV catheter consists of two main assemblies:

- Catheter body
- Imaging Core

The catheter body is comprised of two sections:

- Dual lumen
- Telescoping section (shaft)

The dual lumen section is the "working length" of the catheter. The dual lumen is an over-the-wire (OTW) design containing an imaging core lumen and a guidewire lumen. The telescoping section remains outside of the introducer sheath. The telescoping shaft allows the imaging core to be advanced and retracted for 25 cm of linear movement. The corresponding movement of the transducer occurs inside the imaging core lumen. The catheter body is attached to the telescope shaft via a y-manifold with male/female luer connection. The straight leg of the y-manifold is the guidewire exit port with a female luer thread. The luer thread allows flushing of the guidewire lumen.

The imaging core is composed of a hi-torque, flexible, rotating drive cable with a radial looking ultrasonic transducer at the distal tip. The distal ends of the imaging core and the catheter body are radiopaque for visualization of the imaging plane and the catheter tip. An electro-mechanical connector interface at the proximal end makes the connection to the Motor Drive Unit (MDU) / Instrument. The MDU-catheter interface consists of an integrated mechanical drive hub and electrical connection.

Intended Use/Indications for Use

The Atlantis™ PV Imaging Catheter is intended for ultrasound examination of peripheral pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Device Technology Characteristics and Comparison to Predicate Device

The Atlantis™ PV Imaging Catheter and its predicate device are comprised of a catheter body and an imaging core. They are similar in terms of their intended use, fundamental technology, operating principle, and catheter design. Modifications to the Atlantis™ PV

Imaging Catheter, the subject of this submission, include design, material, and labeling changes.

Non-Clinical Test Results

The performance test results for bench, biocompatibility and sterility testing of the Atlantis™ PV Imaging Catheter demonstrate that the device meets or exceeds the performance requirements for the specified intended use.

Conclusion

The modified Atlantis™ PV Imaging Catheter is substantially equivalent to its predicate device. The test results support the determination that the two devices are substantially equivalent, and confirm the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2008

Boston Scientific Corporation
c/o Ms. Janice Brown
Director, Regulatory Systems
IVUS Technology Center
47900 Bayside Parkway
Fremont, CA 94538-6515

Re: K080272
Atlantis PV Imaging Catheter
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasound Transducer
Regulatory Class: Class II (two)
Product Code: ITX, OBJ
Dated: January 31, 2008
Received: February 1, 2008

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the iLab™, Galaxy2/Galaxy™, and Clearview™ Ultra Intravascular Ultrasound Imaging Systems, as described in your premarket notification:

Atlantis™ PV Imaging Catheter, Model H749364560

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may

be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lisa E. Leveille at (240) 276-4095.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2.0 Indications for Use

510(k) Number: K080272

Device Name: Atlantis™ PV Imaging Catheter

Indications for Use:

The Atlantis™ PV Imaging Catheter is intended for ultrasound examination of peripheral pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080272

Attachment 2.0
Diagnostic Indications for Use Form
Atlantis™ PV Imaging Catheter

Intended Use: Diagnostic ultrasound imaging of fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E
Additional Comments: Cleared under K022860 (November 21, 2002), K041727 (cleared July 23, 2004) and K050684 (cleared May 20, 2005)

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Concurrence of CDRH, Office of Device Evaluation (ODE)